K121049

JUN 27 2012

510(k) Summary: UNIFY™ Dynamic Anterior Cervical Plate System

Company: Globus Medical Inc.
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
(610) 930-1800

Contact: Meriam Youssef
Project Manager, Regulatory Affairs

Date Prepared: April 5, 2012

Device Name: UNIFY™ Dynamic Anterior Cervical Plate System

Classification: Per 21 CFR as follows:
§888.3060: Spinal Intervertebral Body Fixation Orthosis
Product Code: KWQ
Regulatory Class: II, Panel Code: 87

Predicate(s): ASSURE® Anterior Cervical Plate (K040721)
PROVIDENCE® Anterior Cervical Plate (K070775)
XTEND® Anterior Cervical Plate (K092146)
Medtronic ATLANTIS® Anterior Cervical Plate (K063100)
Synthes Vectra™ Anterior Cervical Plate (K051665)

Purpose:
The purpose of this submission is to request clearance for the UNIFY™ Dynamic Anterior Cervical Plate System, a modification of the cleared ASSURE ® Anterior Cervical Plate System.

Device Description:
The UNIFY™ Dynamic Anterior Cervical Plate System consists of plates and variable or fixed angle screws. The plate attaches to the anterior portion of the vertebral body of the cervical spine (C2-C7). The plate allows translation to accommodate bone graft resorption.

UNIFY™ Dynamic Anterior Cervical Plate System implants are manufactured from titanium alloy, as specified in ASTM standards F136 and F1295.

Indications for Use:
The UNIFY™ Dynamic Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),

trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

Technological Characteristics:
The technological characteristics of the UNIFY™ Dynamic Anterior Cervical Plate System are similar to the predicate devices in terms of design, dimensions, intended use, materials, and performance characteristics.

Performance Data:
Mechanical testing (static and dynamic compression, static torsion, and static tension) was conducted in accordance with ASTM F1717 and, the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004. Performance data demonstrate substantial equivalence to the predicate device.

Basis of Substantial Equivalence:
The UNIFY™ Dynamic Anterior Cervical Plate System has been found to be substantially equivalent to the predicates with respect to technical characteristics, performance, design, materials and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Globus Medical, Inc.
% Ms. Meriam Youssef
Project Manager, Regulatory Affairs
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

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Re: K121049
Trade/Device Name: UNIFY Dynamic Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: May 31, 2012
Received: June 01, 2012

Dear Ms. Youssef:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

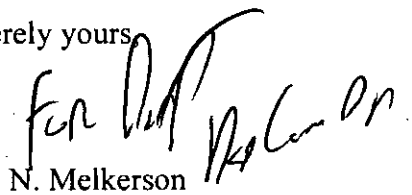
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121049

Indications for Use Statement

510(k) Number: K121049

Device Name: UNIFY™ Dynamic Anterior Cervical Plate System

INDICATIONS:

The UNIFY™ Dynamic Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE ON THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121049